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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/782,266

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07/18/2008

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/782,266	Applicant(s) BESSELINK, PETRUS A.	
	Examiner KATHLEEN SONNETT	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 91-95, 113-122 and 127-142 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 91-95, 113-122 and 127-142 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/18/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 142 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if claim 142 is claiming an additional step of applying a radially outward force to the expandable device or if this is merely an oversight as claim 130 now includes this step.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. **Claims 91-95, 113, 118, 130-139, 141, and 142 are** rejected under 35 U.S.C. 102(e) as being anticipated by Carpenter et al. (US 5,643,314). Regarding claims 113, 122, and 130, Carpenter et al. discloses a method of stabilizing an unsupported section of a passageway comprising providing an expandable device having one or more cells, each of the cells comprising first and second arcuate members (for example, two adjacent rings), placing the device at a passage in the passageway while in a first stable state, and expanding the one or more cells to a transition point defining a geometry of one or more cells at which no additional

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force is necessary to further expand the one or more cells, permitting the one or more cells to continue to expand beyond the transition point without the application of additional force (see entire document, esp. col. 4 ll. 64-col. 5 ll. 20). In particular, Carpenter et al. discloses partially inflating a balloon to apply an expansive force to the inner surface of the stent to overcome the locking action provided on the stent so that the stent is free to self-expand. The transition point geometry is considered the cells' geometry at the point where the lock is freed.

5. Regarding claim 91, the method comprises providing an expandable device with a plurality of cells, at least one cell capable of being expanded between a stable contracted state and a stable expanded state without any stable configurations between the stable contracted state and the stable state (first stable state- contracted and engaged with lock; second stable state- either next lock engaged or fully expanded state depending on how many locks there are and what is being considered the first stable state).

6. Regarding claim 118, Carpenter et al. teaches expanding the device to a first and second stable size.

7. Regarding claims 92, the device does not axial shorten.

8. Regarding claims 93 and 94, the device is tubular and can be considered a liner as it lines a blood vessel.

9. Regarding claims 95 and 130, when an end cell is considered which includes a thicker arcuate member and a thinner arcuate member (22c and the ring next to it), the thinner arcuate member is more flexible since there is less material and is being considered more pliable.

10. Regarding claim 131, when considering the arcuate members in the first stable position, they can be considered to comprise a wave shape because sections of them (for example, half or a quarter of the ring) resemble the peak of a wave.

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11. Regarding claims 132 and 142, the step of expanding comprises expanding the device radially outward.

12. Regarding claims 133-139, the device of Carpenter et al. is a generally tubular stent delivered into a body of a patient.

13. Regarding claim 141, the entire device of Carpenter et al. can be considered a single unit since the cell must comprise first and second arcuate members and may include other elements.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. **Claims 114-117, 119-122, and 127-129** are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpenter et al. Carpenter et al. discloses the invention substantially as stated above but fails to disclose attaching a wrapping or liner to the outer surface of the device or isolating a portion of the passageway with the expandable device. However, expandable, deformable, and elastomeric material grafts, sleeves, or coating applied to stents are well known in the art and the step of attaching such a material to the stent of Carpenter et al. would have been obvious to one skilled in the art as it is sometimes desirable to completely isolate a portion of the body passageway from blood passing through it or increase the biocompatibility of a stent through a graft covering.

16. Regarding claims 119 and 120, each cell assumes a stable collapsed configuration and a stable expanded configuration. In particular, the stent has a portion, when collapsed, that engages a lock and is therefore considered stable as it holds itself in this position. When a

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balloon is used to apply a force to overcome this lock, the stent expands to a stable expanded configuration wherein the next lock is engaged or full expansion (if no more locks) is reached. Carpenter et al. teaches that different configurations can be realized to treat differing vessel diameters (such as tapered configuration) and it would have been within the purview of one skilled in the art to use the device in a manner where the stent, which starts out at a first stable configuration wherein the first lock is engaged, engages the wall of the stent when it reaches its second stable configuration at the second lock.

17. Regarding claim 127, when considering the arcuate members in the first stable position, they can be considered to comprise a wave shape because sections of them (for example, half or a quarter of the ring) resemble the peak of a wave.

18. Regarding claim 128, the device does not axial shorten.

19. Regarding claim 129, when an end cell is considered which includes a thicker arcuate member and a thinner arcuate member (22c and the ring next to it), the thinner arcuate member is more flexible since there is less material.

20. **Claim 140** is rejected under 35 U.S.C. 103(a) as being unpatentable over Carpenter et al. in view of Wiktor (US 4,886,062). Carpenter et al. discloses the invention substantially as stated above but does not expressly disclose locating multiple stents in the passageway such the ends of adjacent stents overlap forming a continuation of the liner element against the inner diameter of the passageway. However, Wiktor teaches that it is well known to employ multiple stents in tandem and further discloses that a balloon and stent assembly can be fed through a previously implanted stent so that a second stent may be implanted downstream of the first stent (col. 5 ll. 3-9). It would have been obvious to one skilled in the art to have modified the method of Carpenter et al. to include implanting several stents within the passageway as taught by Wiktor in order to treat a larger area of a vessel. Regarding the overlapping ends, such a

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modification would have been obvious in order to ensure that no portion of the vessel is untreated between the stents.

Response to Arguments

21. Applicant's arguments, filed 3/18/2008, with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 7/11/2008

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731